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09/606,314

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Richard Fike

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EXAMINER

SCHUBERG, LAURA J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/606,314 | <b>Applicant(s)</b><br>FIKE ET AL. |  |
|                              | <b>Examiner</b><br>Laura Schuberg    | <b>Art Unit</b><br>1657            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 27,36,92-95,103,110,111 and 122-125 is/are pending in the application.
- 4a) Of the above claim(s) 110 and 123-125 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27,36,92-95,103,111,122 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant is requested to note that the Examiner for this application has changed. Future correspondence should be directed to Laura Schuberg, Art Unit 1657, whose contact information can be found below.

### ***Election/Restrictions***

Applicant's election without traverse of species Chinese Hamster Ovary cell and Dulbecco's Modified Eagle's Medium (claims 111 and 125) in the reply filed on 03/06/2009 is acknowledged.

Applicant's election without traverse of Invention I (claims 27, 36, 92-95 and 122-125) in the reply filed on 08/28/2009 is acknowledged.

Claims 27, 36, 92-95, 103, 110, 111, 122-125 are pending. Claims 27, 36, 103, 111, 122 have been amended. Claims 123-125 have been newly added and no claims have been newly canceled.

Claim 110 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/22/2005.

Claims 123-125 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/28/2009.

Claims 27, 36, 92-95, 103, 111 have been examined on their merits.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27, 36, 92-95, 103, 111 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfe (EP 0283942) in view of Fassolitis et al (Applied and Environmental Microbiology 1981), Peebles (US 2,835,586) and Prestrelski et al (US 5,580,856).

Applicant claims an agglomerated mammalian cell culture medium powder prepared by agglomerating a dry powder mammalian cell culture medium with a solvent; wherein said agglomerated powder comprising a biological buffer and recombinant insulin, upon being reconstituted with water, comprises all the necessary nutritive factors for proliferation or cultivation of a mammalian cell *in vitro*. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting in comparison to a medium powder that is non-agglomerated; wherein said

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medium powder exhibits more rapid dissolution in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated.

Applicant further claims the medium powder of any one of claims 92-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder. Applicant further claims the agglomerated cell culture medium powder of claim 27, wherein said solvent is water, serum, aqueous acid or base. Applicant further claims the agglomerated cell culture medium powder of claim 27, wherein said mammalian cell is a Chinese Hamster Ovary Cell, hybridoma cell or human cell; and wherein the biological buffer is N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid (Hepes).

Wolfe teaches a chemically defined basal nutrient medium used for serum-free culture or supplemented with low levels of serum for high and low density culture. The cell culture medium powder taught by Wolfe also comprises a biological buffer, *e.g.*, alpha-glycerolphosphate or N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid (HEPES) (page 2, lines 46-49). Genetically engineered proteins (recombinant proteins) are suggested as suitable for inclusion in a media composition (page 2 lines 39-40). A preferred protein supplement is insulin for murine hybridomas (page 6 lines 5-9). A pH of about 7.0 to about 7.4 is suggested with a pH of about 7.35 being preferred (page 5 lines 12-16).

Wolfe does not specifically teach wherein the powder cell culture media is agglomerated.

Fassolitis et al teach a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial cells or “animal cells” (mammal) using a powdered nonfat dry skim milk filtrate (NDMF) as an animal cell culture medium (page 201, Column 1, under “Preparation of milk fraction”), wherein Fassolitis et al teach a method of making NDMF comprising reconstituting a dry milk powder. On page 200, Column 2, under “Cell culture medium”, Fassolitis et al teach a cell culture medium supplemented with 5% NDMF and HEPES, wherein the pH of the medium was adjusted to 6.8 to 7.4 that is used to propagate epithelial cells (see Table 1 on page 201).

Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture (column 2 lines 13-70). The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting (claims and Column 9, lines 46-54). With regard to the claim limitation “wherein said agglomerated powder upon being reconstituted with water supports the proliferation or cultivation of a mammalian cell *in vitro*” of Claim 27, as evidenced by the teachings Fassolitis the prior art agglomerated dry powder taught by Peebles is considered as an agglomerated mammalian cell culture medium powder that is able to support the proliferation or cultivation of a mammalian cell *in vitro* upon reconstituted with water and inherently having the claim-designated pH range.

Prestrelski et al teach a spray-drying method that is applied to protein compositions in order to stabilize them for long term storage (column 1). Suitable

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proteins include those used in cell culture media compositions such as growth factors and insulin (column 6 lines 40-54).

It would have been obvious for one of ordinary skill in the art to include the agglomerated spray-dried milk powder of Peebles in the media composition of Wolfe as a serum substitute. One of ordinary skill in the art would have been motivated to do so because Wolfe teaches that a serum-free composition is desirable. One of ordinary skill in the art would have had a reasonable expectation of success because Fassolitis teaches that dried milk powder is a suitable substitute for serum in the culture of animal cells. One of ordinary skill in the art would have been motivated to formulate the cell culture media as an agglomerated dry powder because Peebles teaches that it does not require vigorous or prolonged agitation to make a desired stable dispersion and it is easy to remove from a container and poured from a spout without plugging or dusting (column 9 lines 45-57). One of ordinary skill in the art would have had a reasonable expectation of success because Prestrelski et al teach that it is desirable to spray-dry a protein composition containing insulin and growth factors in order to stabilize them for long term storage.

Therefore the combined teachings of Wolfe, Peebles, Fassolitis et al and Prestrelski et al render obvious Applicant's invention as claimed.



### ***Response to Arguments***

Applicant's arguments with respect to claims 27, 36, 92-95, 103, 111 and 122 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments have been addressed in so far as they relate to the new rejection above.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Each of the references cited above provide evidence of what is known in the prior art and demonstrate the motivation and reasonable expectation of success that an artisan of ordinary skill would have to modify the prior art composition to achieve an improved product.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

Laura Schuberg